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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/912,576

07/24/2001

John Thomas Allen

SUREB-57333

6668

39607

7590

08/03/2006

EXAMINER

MCKANE, ELIZABETH L

PETER K HAHN

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SAN DIEGO, CA 92101

ART UNIT

PAPER NUMBER

1744

DATE MAILED: 08/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/912,576

Applicant(s)

ALLEN ET AL.

Examiner

Leigh McKane

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6,7 and 9-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6,7 and 9-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1, 4, 7, 10, 14, 17, 21, 25, 29, 32, 37, 43, and 46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Specifically, the amendments adding the phrase “predetermined configuration” are not supported by the original disclosure. The specification describes only embodiments wherein the articles are “disposed” in a container. There is no mention of placing them in a “predetermined configuration”, which phrase implies a predetermined order.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. Claims 1, 3, 4, 6, 7, and 9-15, 17-35, and 37-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doi (JP 2000312708, machine translation) in view of Ichihara (U.S. 6,030,554).

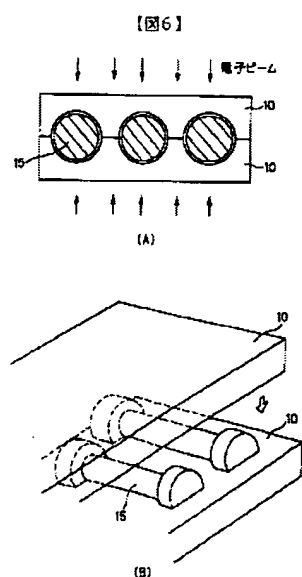
Doi teaches a method and apparatus for electron beam sterilization of articles **15**. Doi discloses that the articles **15** absorb radiation at different positions in accordance with irregularities in the characteristics of the articles at the different positions. See paragraphs

[0004]-[0008]. The articles are provided in a predetermined configuration (side-by-side) within “container” (lower half of **10** in Figure 6A). To provide a uniformity of dosage, a regulator (upper half) **10** is provided to absorb the radiation passing from a source **20** (Figure 5) wherein the regulator **10** is fabricated of a shape and material such that it absorbs radiation passing from the source to the articles at the different positions in the container in accordance with the irregularities in the characteristic of the article at the different positions to maintain the radiation dose at the different positions in the article within particular minimum and maximum

limits. The “container” may be moved past the source on a conveyor along with the regulator.

See paragraph [0009]. The conveyor moves transverse and substantially perpendicular to the radiation. See Figures 5 and 6A. Doi further teaches that the regulator **10** may be fabricated of a material having a “consistency almost equivalent to an irradiated object” and has a shape/geometry complementary to the object. A suggested material is aluminum. See paragraphs [0021] and [0027]; Figure 6A.

While Doi teaches two regulators **10** (wherein the bottom regulator also functions as a



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container for the articles) in Figures 6A and 6B, Doi is silent with respect to a separate container for the articles, which container holds the articles and wherein the two regulators are disposed external to the container. However, Ichihara discloses that “terminal sterilization”, the sterilization of an article within its final packaging, is known in the art in the field of electron beam sterilization. See Abstract. In the invention of Ichihara, an article is placed within a “sealed” (i.e. closed) container which permits transmission of electron beam radiation, but prevents entry of microorganisms into the container. See col.2, lines 31-39. Therefore, once the article is sterilized, it will not be recontaminated by subsequent packaging and/or handling. Likewise, it would have been obvious to one of ordinary skill in the art to package the articles (dialyzers) of Doi prior to sterilization, in order to prevent subsequent recontamination of the dialyzers.

Doi teaches conveying articles **15** past a radiation source **20** in a direction substantially perpendicular to the direction of radiation and the use of a fixture **10** designed to provide a uniform level of absorbed radiation throughout the article. Therefore, although Doi does not specifically disclose that the conveyor moves the articles at a substantially constant speed, it would have been obvious to one of ordinary skill in the art to do so in order to provide a uniform level of absorbed radiation throughout the length of the article. This concept is clearly taught by Doi.

5. Claims 16 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doi in view of Ichihara as applied to claims 15 and 32 above, and further in view of Peck et al. (U.S. 5,590,602).

Doi is silent with respect to spacing adjacent containers and fixtures by a particular distance when being moved past the radiation source. Peck et al. teaches a method and apparatus for electron beam sterilization of articles wherein the articles are conveyed within containers that are spaced from adjacent containers to achieve “optimum article throughput efficiency” (col.5, lines 19-30). Peck et al. further discloses that in order to “most efficiently utilize the energy of the radiation beam emitted by the radiation source **10**, the spacing between the article carriers **17** as they are transported by the process conveyor **14** past the radiation source **10** must be as small as practically possible.” See col.5, lines 61-65. Therefore, it would have been obvious to space adjacent containers and fixtures being conveyed by the conveyor of Doi by a particular distance within particular limits so as to “most efficiently utilize the energy of the radiation beam emitted by the radiation source”.

As to claim 36 specifically, Doi teaches conveying articles **15** past a radiation source **20** in a direction substantially perpendicular to the direction of radiation and the use of a fixture **10** designed to provide a uniform level of absorbed radiation throughout the article. Therefore, although Doi does not specifically disclose that the conveyor moves the articles at a substantially constant speed, it would have been obvious to one of ordinary skill in the art to do so in order to provide a uniform level of absorbed radiation throughout the length of the article. This concept is clearly taught by Doi.

Response to Arguments

6. Applicant's arguments filed 6 June 2006 have been fully considered but they are not persuasive.

7. On page 22 of the Response, Applicant argues that “Ichihara does not remedy the failure of Doi because Ichihara also fails to disclose attaching a dose adjuster externally to a container that holds the articles.” The Examiner respectfully disagrees. If Ichihara were to teach all that Applicant suggests is necessary, Ichihara would be an anticipatory reference. Anticipation is not needed to rejection the claims. As set forth in the rejection, Ichihara was used in combination with Doi to illustrate the *obviousness* of first enclosing the articles sterilized by the method and apparatus of Doi.

8. Moreover, although Applicant contends that housing a plurality of articles “provides significant advantages not recognized by the cited references,” it has been held that where an invention is unpatentable under 35 U.S.C. 103, it is immaterial that applicant may have disclosed an obvious or unobvious further purpose or advantage for the invention. See In re Graf, 145 USPQ 197 (CCPA); In re Finsterwalder, 168 USPQ 530 (CCPA 1971). Indeed, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

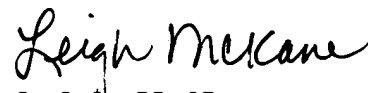
Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The examiner can normally be reached on Monday-Friday (5:30 am-2:00 pm).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Leigh McKane
Primary Examiner
Art Unit 1744

elm
1 August 2006